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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/575,745	PINTO, YIGAL M.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/17/07 & 12/07/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Currently, claims 1-20 are pending and under examination.

Sequence Compliance

1. The specification contains several nucleotide/amino acid sequences throughout the specification which are encompassed by the definitions for nucleotide/amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) and which must conform with the sequence rules for all applications that include nucleotide/amino acid sequences. In the instant application the specification discloses nucleotide/amino acid sequences on pages 12, 23, 24, 34 and 35 and there has been no CRF submitted or paper copy of the "Sequence listing". Further, the sequences listed in the specification do not include sequence identifiers. Additionally, Applicants are responsible for meeting compliance with any sequence the Examiner may have inadvertently missed. APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R. 1.821-25. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

Appropriate correction is required (see attached notice to comply).

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example, page 16 of the specification discloses a hyperlink.

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4. Claim 1 step (d) is objected to because of the following informalities: the claim recites "the marker is indicative of a risk" and then recites "For developing hypertensive end organ damage". This causes a fragmented sentence in the claim. It is recommended to change to -- the maker is indicative of a risk of developing hypertensive end organ damage.--. Appropriate correction is required.

5. In claim 7, it appears that "non-myocytal" should be --non-myocytical--, consistent with the other claims.

Claim Rejections - 35 USC § 112

6. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the inventions.

Claim 1, step (b) is indefinite in reciting "determining the level of at least one non-myocytical marker" because the term "determining" appears to intend a mental step; hence, it is unclear if applicant actually intends positive active methods step in the claim. It is suggested but not required to delete the term "determining" and replace it with --detecting--.

Claim 1, step (d) is indefinite in reciting "determining" because the term "determining" appears to intend a mental step; hence, it is unclear if applicant actually intends positive active methods step in the claim. Further, it is unclear how the level results in an indication that the subject is at risk of developing hypertensive end organ damage.

Claim 1, step d) is also indefinite in reciting "determining whether the level of the maker is indicative of risk"; because it implies an interpretive clause that does not positively define how a determination is made and how the results of the test are correlate to an indication of a risk. The claim does not make clear how to determine whether the results are indicative of or correlated to a risk of developing hypertensive end organ damage. Step (d) as recited does not even require the use of the standard recited in step (c). Is the comparison to the standard somehow used to correlate a risk? Does an increase or a decrease in the detected marker compared to the standard correlate to the indication? Does the mere presence or absence of the marker indicate a risk of developing hypertensive end organ damage?

Although the claims are read in light of the specification, the limitations disclosed in the specification are not read into the claims.

Claims 7-10 provide for the use of one or more non-myocytal markers for identifying a subject at risk of developing congestive heart failure and for the use of galectin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 11 provides for the use of galectin-3 and/or modulators for the manufacture of a medicament for the prevention and/or treatment of hypertensive end organ damage, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 12 provides for the use of thrombospondin-2 and/or modulators thereof for the manufacture of a medicament for the prevention and/or treatment of hypertensive end organ damage, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 18 is indefinite because it is unclear how a non-myocytical marker comprises a combination of a galectin-3 and a thrombospondin-2 molecule. Is the non-myocytical marker a complex molecule which somehow has galectin-3 bound to thrombospondin-2? Further, such a molecule is not known in the art. Also the claim is indefinite in reciting improper Markush language in reciting "the non-myocytical marker comprises galectin-3, thrombospondin-2 or combinations thereof". Perhaps applicant intends the non-myocytical marker is selected from the group consisting of galectin-3, thrombospondin-2 and combinations thereof.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 4, 6, 15, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Woo (US 2002/0076738).

Woo disclose a method comprising obtaining a biological sample such as blood from a patient (subject) and determining the concentration of a marker such as galectin-3 (non myocytical marker) in the sample and comparing the level of the marker to the level of the marker in a normal human (standard control) and making a determination of the results (e.g. abstract, page 3). Woo discloses that the level of the marker can be measured by enzyme-linked Immunosorbent assay (ELISA) (e.g. p. 3). Woo discloses that the blood sample can be a peripheral blood sample (e.g. para 0054).

Further, with respect to the recitation "determining whether the level of the marker is indicative of a risk. For developing hypertensive end organ damage", the body of the claim provides an interpretive "determining" clause and fails to recite how indication of a risk for developing hypertensive end organ damage is actually determined based on the detected levels from the subject and the standard. The

process steps that are positively recited in the claims are a step of obtaining a sample, and provide a result determining a level of a non myocytical marker in a sample and comparing the level to a standard level and determining results. Thus, Woo reads on the claim because Woo teaches obtaining a sample from a subject and determining results of a level of marker and comparing the marker to a standard and determining a result and as stated above it is unclear how (see 112 2nd rejection above) the determining step is performed or how it is correlated to a risk of developing hypertensive end organ damage. In the instant case, Woo performs every active method step and when every active method step has been performed the prior art method is met. For the reasons stated above Woo reads on the instantly recited claims.

9. Claims 1-3, 6-8, 13-15, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Doyle et al (US 2006/0166276).

Doyle et al disclose methods of diagnosing, predicting and determining risk for congestive heart failure (hypertensive end organ damage) (abstract, para 0021, 0032, 0103, 0104). Doyle et al disclose obtaining a sample of blood from a subject (para 0114) and determining the level of a pulmonary surfactant marker such as surfactant protein-B (non myocytical marker) in the sample and comparing the level to a control level (standard level) and determining an increase to correlate a diagnosis or risk for congestive heart failure (p. 9). Doyle et al disclose that the sample can be a plasma sample that an ELISA assay can be used to determine the level of the marker (e.g. para 0158, 0202, 0221, 0236 and 0237).

Further, with respect to the recitation "determining whether the level of the marker is indicative of a risk. For developing hypertensive end organ damage", the body of the claim provides an interpretive "determining" clause and fails to recite how indication of a risk for developing hypertensive end organ damage is actually determined based on the detected levels from the subject and the standard. The process steps that are positively recited in the claims are a step of obtaining a sample, and provide a result determining a level of a non myocytical marker in a sample and comparing the level to a standard level and determining results. Thus, Doyle et al reads on the claim because Doyle et al teaches obtaining a sample from a subject and determining results of a level of marker and comparing the marker to a standard and determining a result and as stated above it is unclear how (see 112 2nd rejection above) the determining step is performed or how it is correlated to a risk of developing hypertensive end organ damage. In the instant case, Doyle et al performs every active method step and when every active method step has been performed the prior art method is met. For the reasons stated above Doyle et al reads on the instantly recited claims.

10. Claims 1-3, 5, 6, 13-15 and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by McCarthy (US 2003/0166017).

McCarthy et al disclose methods comprising obtaining a biological sample such as blood from a patient (subject) and determining the level of a maker in the sample. McCarthy et al disclose the marker can be thrombospondin-2 (non myocytical marker). McCarthy et al disclose comparing the level of the marker to the level of the marker in a

known control (standard control) and making a determination of the results (e.g. para 0043, 0184, 0241-0254, 0260, 0261). McCarthy et al discloses that the sample can be a plasma sample and that the level of the marker can be determined with an ELISA assay (p. 20, p. 26).

Further, with respect to the recitation "determining whether the level of the marker is indicative of a risk. For developing hypertensive end organ damage", the body of the claim provides an interpretive "determining" clause and fails to recite how indication of a risk for developing hypertensive end organ damage is actually determined based on the detected levels from the subject and the standard. The process steps that are positively recited in the claims are a step of obtaining a sample, and provide a result determining a level of a non myocytical marker in a sample and comparing the level to a standard level and determining results. Thus, McCarthy et al reads on the claim because McCarthy et al teaches obtaining a sample from a subject and determining results of a level of marker and comparing the marker to a standard and determining a result and as stated above it is unclear how (see 112 2nd rejection above) the determining step is performed or how it is correlated to a risk of developing hypertensive end organ damage. In the instant case, McCarthy et al performs every active method step and when every active method step has been performed the prior art method is met. For the reasons stated above McCarthy et al reads on the instantly recited claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

7/3/09